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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/548,998	04/14/2000	Richard C. Ebersole	BC1002 US NA	7991
23906	7590	12/23/2003	EXAMINER	
E I DU PONT DE NEMOURS AND COMPANY LEGAL PATENT RECORDS CENTER BARLEY MILL PLAZA 25/1128 4417 LANCASTER PIKE WILMINGTON, DE 19805			LAMBERTSON, DAVID A	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 12/23/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/548,998

Applicant(s)

EBERSOLE ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 31, 2003 has been entered.

Claims 1 and 5 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed June 25, 2003, that is not addressed in this action has been withdrawn.

Information Disclosure Statement

An inspection of the application indicates that there is an IDS of record in the file that appears to have not been considered. The IDS filed January 7, 2002 was marked "Duplicate Copy" by the previous examiner. However, there is no record that many of the references cited on the IDS were considered. As such, the IDS has been considered on the record, and a signed and initialed copy of the form PTO-1449s are attached to this Office Action. It is noted that the first reference on the second page of the IDS has been crossed through as a duplicate reference that has already been considered on the record.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 5 recites the terminology "provided however that the strain is not *Dehalococcoides ethenogenes* DHE-195" in the body of the claim. However, there is no support for this negative limitation in the specification. As such, the terminology represents new matter.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Applicant claims any bacterial species having the sequence defined as SEQ ID NO: 8 in the instant specification, and having the ability to dechlorinate chlorinated compounds. The claims read on a broad genus of bacterial strains with a particular sequence and the ability to dechlorinate chlorinated compounds.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by

disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show applicants were in possession of the claimed genus. In the instant case, the specification does not sufficiently describe a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics.

Applicant claims a bacterial strain having SEQ ID NO: 8 and the ability to dechlorinate chlorinated compounds by function only, without any disclosed or known correlation between the elements and their function. The specification only provides teachings regarding a few individual bacterial strains of the *Dehalococcoides* genus and a particular sequence that has been characterized as being present in that genus of bacteria. The specification does not teach a representative number of bacteria having SEQ ID NO: 8 and the ability to dechlorinate chlorinated compounds because the skilled artisan cannot envision what bacteria meet the limitations set forth in a claim. For instance, Holoman *et al.* (IDS reference) teach a number of bacteria that have the ability to dechlorinate chlorinated compounds, including one that is from the *Dehalococcoides* genus along with a number of different genera of bacteria, yet they have not sequenced the genomes of these organisms. The skilled artisan could not envision if these strains meet the limitations of the claim because the specification does not describe the claimed strains in such detail that the skilled artisan would be able to envision what strains meet the limitations of the claim. Furthermore, there are a number of factors that determine an organisms ability to perform a biological function that are unrelated to 16S rDNA, including the ability to encode the enzyme which is functional in the dechlorination process. The instant specification does not

describe these factors, therefore the skilled artisan could not envision a bacteria having both the sequence identified as SEQ ID NO: 8 as well as the functional activity to dechlorinate chlorinated compounds based on the teachings of the instant specification. Because the skilled artisan cannot envision a sufficient number of embodiments of the instant invention from the instant specification, the instant specification has not satisfied the written description for the claimed genus

The prior art does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the prior art that allows one of skill in the art to envision a representative number of bacteria having both SEQ ID NO: 8 and the functional ability to dechlorinate chlorinated compounds by disclosing the necessary structure-function features of said bacteria. Thus, the skilled artisan cannot rely on the prior art to envision a sufficient number of embodiments of the instant invention to see that the applicant was in possession of the claimed genus.

In conclusion, the claim reads on a broad genus of bacterial strains, many of which may not have been identified in the instant specification or the prior art. The instant claim does not involve a premeditated genetic modification that conveys a functional activity on a cell, instead reading on bacteria that are waiting to be discovered. In fact, the prior art (Holoman *et al.*) discloses a number of bacterial strains having the ability to dechlorinate chlorinated compounds, but which have not been sequenced for the presence of SEQ ID NO: 8. This reference may indeed read on and anticipate the instant claim, but for the fact that the strains have not been sequenced. This is the definition of a "reach-through" claim, wherein a claim is designed to cover not what is disclosed in the specification, but what can be *identified* with the teachings of

the instant specification. The ability to potentially identify the claimed subject matter is not sufficient to meet the written description requirement for that very reason: the subject matter of the claim is not described in the specification. Therefore, instant claim 5 does not satisfy the written description requirement of 35 USC § 112, first paragraph.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988), and the most relevant factors are indicated below:

Nature of the invention. The nature of the invention is *any* bacterial strain having the sequence identified as SEQ ID NO: 8 and the ability to dechlorinate a chlorinated compound. The claims encompass strains that are not described in the specification, and indeed may not have been identified at all. Additionally, the claims read on bacterial strains that have been described, but may not yet have been characterized as having SEQ ID NO: 8 (although such a strain may very well contain the sequence). Thus, the invention encompasses a “reach-through” claim that attempts to gain patent coverage for subject matter that cannot be made in view of the instant

specification alone. It is noted specifically that the ability to “identify” is not equivalent to the ability to “make and use,” which is the standard for meeting the enablement requirement.

Scope of the invention. The scope of the invention is very broad, encompassing any bacterial strain having SEQ ID NO: 8 and the ability to dechlorinate a chlorinated compound. This includes strains that have not been identified or described in the specification (or anywhere), as well as known strains that have the functional ability to dechlorinate a chlorinated compound, but have not yet been sequenced for the presence of SEQ ID NO: 8.

State of the art. The state of the art indicates that a number of strains having the ability to dechlorinate a chlorinated compound are known in the prior art (Holoman *et al.*; see the entire document, especially the Abstract; cited on an IDS). These bacteria encompass a broad range of genera, including *Dehalococcoides*, *Clostridium*, etc. Whether or not these strains contain SEQ ID NO: 8, however, is unknown because the genomes of these bacteria have not been sequenced or probed for the presence of the sequence. Because the skilled artisan cannot ascertain how to make the strains that are claimed in the instant specification, the skilled artisan would not be able to ascertain if the strains disclosed in the art would anticipate the instant claim.

Number of working examples and Guidance provided by applicant. The instant specification teaches that SEQ ID NO: 8 is a consensus sequence established by comparing the sequences of 5 specific bacterial strains, all of which are of the genera *Dehalococcoides*. There is no indication that this sequence is present in any other bacteria that has the ability to dechlorinate a chlorinated compound, such as a *Clostridium* species. As such, the skilled artisan would be unable to make a *Clostridium* species that has SEQ ID NO: 8, and therefore the ability to dechlorinate a chlorinated compound. Similarly, the skilled artisan would be unable to make

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an *E. coli* bacterial cell that has the ability to dechlorinate a chlorinated compound because it is unclear that such a bacteria can be made from the instant specification. Thus, the instant specification does not provide sufficient teachings to make the claimed genus of bacterial strains set forth in claim 5

Unpredictability of the art and Amount of experimentation required. The claimed invention requires a vast amount of empirical experimentation and is highly unpredictable in nature. The art is unpredictable because there are a number of bacterial strains that were known before the instant invention that have the ability to dechlorinate a chlorinated compound; however it is unknown whether or not these strains contain SEQ ID NO: 8 because the genomes of these organisms have not yet been sequenced (see for instance Holoman *et al.* as indicated above). Because the skilled artisan cannot immediately tell if any of these organisms meet the limitations of the claim, the claimed invention itself must be unpredictable because the skilled artisan cannot be certain of what meets the limitations of the claim. Furthermore, the skilled artisan would be unable to make such a strain without undue trial and error experimentation. Such experimentation would require the skilled artisan to first isolate a new bacterial strain, test it for its ability to dechlorinate a chlorinated compound, and then determine whether or not SEQ ID NO: 8 was present in the genome of the organism before knowing whether or not the organism that was identified even met the limitations of the claim. Then, and only then, would the skilled artisan know how to make the broad genus of claimed strains. Although the skilled artisan would be able to identify a bacteria that meets the limitations of the claim through the empirical experimentation set forth above, the ability to identify is not the standard for enablement. Rather

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the ability to identify merely sets forth an invitation to experiment, which does not satisfy the enablement requirement of 35 USC § 112, first paragraph.

In conclusion, claim 5 is not enabled because the skilled artisan cannot be apprised of what bacterial strains meet the limitation of the claim without undue trial and error experimentation of an empirical and unpredictable nature. Since it cannot be predicted what bacterial strains will have SEQ ID NO: 8 *and* the ability to dechlorinate a chlorinated compound, the claim cannot be enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 lacks a period. Therefore the claim is indefinite because it is unclear if there are additional limitations to be set forth in the claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 31 of copending Application No. 10/061,071 (henceforth the '071 application). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 31 of the '071 application sets forth claim language that anticipates the instant claim. Specifically, claim 31 also reads on an isolated 16S rDNA sequence indicative of a dechlorinating bacteria strain, wherein the sequence can be a sequence identical to the elected sequence (SEQ ID NO: 8) of the instant invention, or a sequence that is completely complimentary thereto.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson, Ph.D.
AU 1636



JAMES KETTER
PRIMARY EXAMINER